K121485

HemCon Medical Technologies Europe Ltd., 6 Courtyard Business Centre, Orchard Lane, Blackrock, Co. Dublin, Ireland

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AUG 2 1 2012

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Trade Name:	GuardIVa® Antimicrobial Hemostatic IV Dressing
Common Name:	Wound Dressing
Classification:	Unclassified
Classification Name:	Dressing
Product Code:	FRO
Predicate Device(s):	GuardIVa™ Antimicrobial Hemostatic IV Dressing (K093729)
Company Name:	HemCon Medical Technologies Europe Ltd.
Company Address:	6 Courtyard Business Centre, Orchard Lane, Blackrock, Co. Dublin Ireland
Contact Person:	Barbara M^{c}Grath Regulatory Affairs Manager
Contact Phone:	(503) 245.0459 x120
Contact Fax:	(503) 245.1326
Date of Preparation:	17 Aug 2012

Description of the Device:

The HemCon® GuardIVa® Antimicrobial Hemostatic IV Dressing is a sterile hydrophilic, absorptive polyurethane sponge dressing impregnated with the broad spectrum antimicrobial agent chlorhexidine gluconate (CHG) and HemCon's proprietary hemostatic agent, microdispersed oxidized cellulose (m•doc™). The dressing is backed with a non-stick polyurethane film and is individually packaged in a peelable low density polyethylene (LDPE) and Tyvek® pouch. The dressing is provided both sterile and non-sterile. The sterile version of the dressing is terminally sterilized with gamma irradiation to a sterility assurance level (SAL) of 10^{-6}.

The hemostatic properties of m•doc™ enhances the ability of the foam to control surface bleeding from percutaneous catheters and vascular access sites.

CHG is a well known antiseptic agent with broad spectrum antimicrobial and antifungal activity against a wide range of gram positive and gram negative organisms yeast and fungi (See Table 1). The CHG antimicrobial agent protects the dressing from microbial colonization.

GuardIVa® is an adjunct to infection control measures by providing sustained IV site protection, GuardIVa® has not been clinically tested for its ability to reduce catheter related blood stream infections (CR-BSI).

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Table 1: Antimicrobial Efficacy of GuardIVa® assessed using Log Reduction of Organisms

Organism	Gram Stain	24 Hr Log Reduction	7 Day Log Reduction
Staphylococcus aureus (MRSA)	+	>4.0	>4.0
Staphylococcus epidermidis (MRSE)	+	>4.0	>4.0
Enterococcus faecium (VRE)	+	>4.0	>4.0
Pseudomonas aeruginosa	-	>4.0	>4.0
Acinetobacter baumanii	-	>4.0	>4.0
Klebsiella pneumoniae	-	>4.0	>4.0
Escherichia coli	-	>4.0	>4.0
Candida albicans	N/A	>4.0	>4.0
Aspergillus niger	N/A	>4.0	>4.0

Intended Use:

The HemCon GuardIVa® Antimicrobial Hemostatic IV Dressing is intended for use as a hydrophilic wound dressing to absorb exudate, cover and protect catheter sites. Common applications include IV catheters, other intravenous catheters and percutaneous devices. It is also indicated for control of surface bleeding from percutaneous catheters and vascular access sites.

Indications for Use (Rx):

The HemCon GuardIVa® Antimicrobial Hemostatic IV Dressing is intended for use as a hydrophilic wound dressing to absorb exudate, cover and protect catheter sites. Common applications include IV catheters, other intravenous catheters and percutaneous devices. It is also indicated for control of surface bleeding from percutaneous catheters and vascular access sites.

Technological Characteristics:

The version of GuardIVa® Antimicrobial Hemostatic IV Dressing that is the subject of this notification is technologically identical to the currently marketed GuardIVa® dressing originally cleared in K093729. The proposed changes to the product information are based on additional performance testing completed by HemCon and do not affect the fundamental scientific technological characteristics of the product.

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Summary of Performance Data:

Biocompatibility

Biocompatibility has been demonstrated per ISO 10993. Categorization of the device by nature of body contact deduces the GuardIVa® Antimicrobial Hemostatic IV Dressing is a surface-contacting device that contacts breached or compromised surfaces. The duration of contact may be prolonged at more than 24 hours, but no more than 30 days. Cytotoxicity, irritation and sensitization testing was performed by contract testing laboratories under GLP conditions per standard protocols.

In Vivo Efficacy - Dermal Wound Healing Studies

Two independent *in vivo* dermal wound healing studies in rats were performed by contract testing laboratories under GLP conditions to demonstrate that the CHG in GuardIVa® does not adversely affect the rate of wound healing compared to un-treated wounds. Wounds treated with GuardIVa® healed at a rate comparable to untreated wounds with no visible signs of erythema and with an edema response comparable to that of un-treated wounds. Another commercially available CHG containing sponge dressing was used as a control and it did have a pronounced adverse effect on healing and edema.

In Vivo Efficacy - Hemostatic Properties of GuardIVa®

The haemostatic efficacy of GuardIVa® Antimicrobial Hemostatic IV Dressing was tested in comparison to standard gauze dressing in a rabbit ear model. The time to hemostasis was significantly reduced in wounds treated with GuardIVa® (48 s) compared to standard gauze (113 s). Furthermore, up to seven times less blood loss was observed for wounds treated with GuardIVa® (0.17 g) compared with standard gauze (1.30 g).

In Vivo Efficacy - Suppression of Skin Flora Re-growth in Healthy Volunteers

A study, conducted independently by the Centre for Laboratory Activities in Public Health Protection and Promotion, National Reference Laboratory for Disinfection and Sterilization, National Institute of Health, Prague, Czech Republic, on healthy human volunteers, demonstrated the ability of GuardIVa® to suppress skin flora re-growth for up to 10 days, maintaining skin flora at a level equivalent to that observed immediately following preoperative skin preparation (70% isopropyl alcohol solution).

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Sustained Antimicrobial Efficacy - 7 Day Log Reduction Values.

The sustained antimicrobial efficacy of GuardIVa® Antimicrobial Hemostatic IV Dressing, for up to 7 days, was demonstrated *in vitro* using a modified version of the AATCC Test Method 100-2004 "Assessment of Antibacterial Finishes on Textiles". GuardIVa® dressings were tested in triplicate against seven [7] bacterial strains, S. *aureus* (MRSA), S. *epidermidis* (MRSE), E. *faecium* (VRE), P. *aeruginosa*, A. *baumanii*, K. *pneumoniae* and E. *coli*, the diploid yeast C. *albicans* and the fungus A. *niger*. A greater than 4 log reduction in microbial count was observed for all test organisms.

Table 2: Organisms causing CRBSI and their prevalence

Organism	Prevalence	GuardIVa Test Organism
Coagulase-negative staphylococci	31%† - 37%‡	Staphylococcus epiderrmidis
Staphylococcus aureus	20%† - 22%‡	Staphylococcus aureus (MRSA)
Enteric Gram negative bacilli	11%† - 12.4%‡	Escherichia coli, Klebsiella pneumoniae
Yeast (Candida species)	9%† – 9.3%‡	Candida albicans
Pseudomonas	5.5%‡	Pseudomonas aeruginosa
Enterococci and Streptococci	4.9%‡ - 9%†	Enterococcus faecium,
Other	8.9%‡ - 20%†	Acinetobacter baumanii

† Data from Abad & Safdar (2011)
‡Data from Fletcher (2005)

Antimicrobial Efficacy - Zone of Inhibition Measurements

Kirby-Bauer Zone of Inhibition (ZoI) measurements were used to demonstrate the bactericidal or bacteriostatic properties of GuardIVa® Antimicrobial Hemostatic IV Dressing against a range of micro-organisms over a 7 day period (See Table 3). Individual test articles were placed onto agar plates and incubated for 24 hr at 35 – 37°C. The area under the test articles was swabbed and the swab was transferred onto sterile agar plates. The test articles were then placed on a freshly inoculated agar plates and the procedure repeated for 7 days. Growth from the swabs taken from the test articles indicated bacteriostatic action (slowed growth over 7 days) of the CHG in GuardIVa®, while no growth over 7 days indicated bactericidal action. GuardIVa® Antimicrobial Hemostatic IV Dressing was shown to be bactericidal against five of the test organisms (MRSA, MRSE, VRE, *E.coli* and *K. pneumoniae*) and bacteriostatic against the other three organisms (*P. aeruginosa, A. baumanii* and *C. albicans*).

Table 3: Bactericidal and Bacteriostatic properties of GuardIVa® assessed using Kirby-Bauer Zone of Inhibition Measurements

Organism	
Staphylococcus aureus (MRSA)	Bactericidal
Staphylococcus epidermidis (MRSE)	Bactericidal
Enterococcus faecium (VRE)	Bactericidal
Escherichia coli	Bactericidal

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Organism	
Pseudomonas aeruginosa	Bacteriostatic
Acinetobacter baumanii	Bacteriostatic
Klebsiella pneumoniae	Bactericidal
Candida albicans	Bacteriostatic

Sterility

A sterility validation for GuardIVa® Antimicrobial Hemostatic IV Dressing was completed following ISO 11137:2006 requirements to demonstrate a 10^{-6} SAL using the VD_{max}^{25} method.

Conclusion:

GuardIVa® Antimicrobial Hemostatic IV Dressing is technologically identical to the predicate device. The conclusion drawn from the technological characteristics and performance data is that the GuardIVa® Antimicrobial Hemostatic IV Dressing is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

HemCon Medical Technologies Europe Limited
% HemCon Medical Technologies, Incorporated
Ms. Barbara McGrath
Manager of Regulatory Affairs
10575 SW Cascade Avenue, Suite 130
Portland, Oregon 97223

AUG 2 1 2012

Re: K121485
Trade/Device Name: GuardIVa® Antimicrobial Hemostatic IV Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 18, 2012
Received: July 19, 2012

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

Applicant: HemCon Medical Technologies Europe Ltd.

510(k) Number: K121485

Device Name: GuardIVa® Antimicrobial Hemostatic IV Dressing

Indications for Use (Rx):

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Prescription Use ☒ (Part 21 CFR 801 Subpart D) AND/OR **Over-The-Counter Use** ☐ (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause M/M

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121485